Mehmet Baharoglu – Logistics and Export Business Development Director and Beril Tezcanli – Quality Group Director and QP, Birgi Mefar Group, Turkey



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Mehmet Baharoglu and Beril Tezcanli of Birgi Mefar Group, Turkey's leading CMO with a proven track record and experience of production across all small and medium volume injectable dosage forms for local, international and multinational pharmaceuticals, provide insights into the Group's unrivalled expertise and competitive advantages as well as its ambitious internationalization strategy.

The first manufacturing of Sanofi Pasteur's Tetraxim / Pentaxim (Tetravalent vaccine) as well as Pfizer's PREVNAR 13® *(Pneumococcal 13-valent Conjugate Vaccine)* manufacturing which begun in your facility almost 10 years ago as the first company to produce vaccines in Turkey for global companies. Could you introduce the Group to our international readers, and particularly its toll-manufacturing arm Mefar?

Since its founding over 55 years ago, Birgi Mefar has continuously been developing itself by investing in its people, infrastructure and its technological capabilities. During 2011, the founding Birgi Family sold their controlling interest to a private equity consortium with Baharoglu Family. Eager to usher in a new era of growth, its new owners' primary objective was to ensure that Birgi Mefar's admired experience and expertise continued to develop in the foreseeable future.

Birgi Mefar is an integrated group of three companies. **Mefar,** the toll-manufacturing arm of the group established in 1985, stands out as Turkey's leading CMO for small and medium volume injectable dosage forms in ampoules, lyophilized vials & ampoules, vial, BFS (blow-fill-seal) and PFS (pre-filled-syringes) with full-service analytical labs to support activities such as scale-up batch production, stability studies and analytical transfer and validation.

Mefar prides itself on having one of the most comprehensive portfolios in the world in its areas of focus, even in comparison to the largest CMOs globally. As a specialized manufacturer of sterile and injectable solutions, Mefar leverages the unique expertise and flexibility of its sister company, **Birgi,** Turkey's largest primary packaging manufacturer of empty ampoules and empty vials which was founded in 1963.

Mefar utilizes around 60 percent of Birgi production, while the rest is exported to international customers based mainly in the EU. the group also includes a GMP logistics operation, Defar

The strategy of the Group has always been to develop itself into a vertically integrated player, and these synergies flowing from this provide our customers with an unrivalled level of flexibility with regards to production planning while giving the Group a competitive edge guaranteeing on-time delivery. To summarize, Birgi Mefar's scope of services covers laboratory and regulatory support services (Mefar), the production of empty ampoules and vials (Birgi), toll manufacturing and packaging of products (Mefar), and – finally –services through Defar. We are truly able to operate as a one-stop shop service provider for a large part of the Pharmaceutical value chain, which has caught the attention of 100+ leading, domestic and global customers.

Birgi Mefar is already established as Turkey's leading CMO group – in this context, what are your strategic priorities to further grow Mefar moving forward?

A key priority for us is to increase our exports and our geographic reach, the international activities already make up around 35 percent of Mefar's turnover. With regard to GMP certifications, we received EMA GMP certification in 2016 (sterile, ampoule, vial, BFS, and lyophilized products) and we had GMP certifications from more than 10 countries including SFDA, Russian Federation, CECMED and many others.

In the local market, we continue to consolidate and strengthen our relationship with Turkey's Ministry of Health, as a key enabler of the government's vision to locally manufacture high-technology products. As a matter of fact, MoH relies on us for complex products' localization, even

on a very short notice and we provide all the support companies and the MoH need to localize their products.

Birgi Mefar has indeed made a name for itself by putting into motion some of the country's most complex manufacturing projects. On which basis do you select the projects the company engages itself into?

Whether a given project is related to localization policies or not, Mefar's policy always is either to be the sole manufacturer in Turkey or – at least – among the first two companies chosen for the production of any given molecule.

Our impressive track record sustains this approach: Birgi Mefar was the first company in Turkey – to locally produce vaccines, through partnerships with Pfizer and Sanofi Pasteur. On the Blow-Fill-Seal (BFS) side, we also proudly stand as Turkey's frontrunner in the manufacture of inhalers as well as eye-drops – These are just a few of many examples across our portfolio.

This wealth of experience has also honed our ability to complete effective and complex technology transfers within record timelines.

The CMO space is particularly competitive at the global level. What will be your priorities to further internationalize the company, as well as Mefar's competitive advantages to fulfill this vision?

Over 30 percent of our turnover comes from international operations, and our current partners hail from over 37 countries, so we are far from being newcomers on the global stage. We already are well known among parts of the global industry and – through decades of experience with international clients – have built a strong customer network, which we aim to further leverage to increase our international business through making our customers' more competitive in their given markets

Although we truly operate on a customer-specific basis, we can draw on three main categories of international customers: first, international companies with operations in Turkey aiming to cater to both the Turkish and foreign markets. International companies without a commercial and/or manufacturing presence in Turkey, and – so far – most of these partners are European companies, with Germany and the United Kingdom being important markets for us. In this segment, we not

only partner with pharmaceutical companies and Europe-based CMOs have also chosen to outsource manufacturing services to Mefar. Finally, we will leverage also our 10 GMP certifications to support domestic companies in their ever-growing export ambitions – this is the third vertical of our international growth plans

Birgi Mefar's quality, expertise, experience., and quality certifications, Turkey's strategic location at the doorstep of the EU stands as a competitive advantage that should not be overlooked along with the Turkish MoH supporting the Turkish Pharmaceutical companies by being a member of PICs.

You may be surprised to learn that we are in discussion with Indian manufacturers and CMOs looking to export products from our facilities to Europe, an option they deemed attractive even in light of India's particularly competitive manufacturing costs. When you add Turkey's strategic location to our country's highly skilled labor force and long-standing experience in pharma manufacturing. The advantage we offer become clear especially when compared to the cost of manufacturing in Europe. In this regard, we can compete with any player displaying the same quality and regulatory certifications, regardless of the country of origin.

What do you see as the most crucial differentiators for Big Pharma companies when it comes to choosing their outsourcing partners?

After 20 plus years of experience partnering with several of the most prestigious pharma companies, our understanding is that quality, transparency and compliance utmost importance in the eyes of our partners – to some extent even higher than pricing – as they cannot take any risks when it comes to outsourcing crucial part of their global operations.

For Birgi Mefar, merely meeting the requirements is not enough: we truly aim to exceed both regulatory and customers' expectations and be ahead of the curve, especially when it comes to quality compliance of implementing regulatory changes. Besides the countless regulatory inspections we have successfully passed, our facilities are constantly inspected by our partners, which include the world's leading pharma companies.

In this regard, we also hold an impressive number of certifications, which range from quality, regulatory to health and safety issues. For instance, we were the first company in Turkey's pharma sector and among the first in Europe to be certified with the ISO 45001 Occupational Health and Safety Management System. In the same vein, we were recently recognized as the "Best Environmentally Friendly" company in Turkey, thereby showcasing Mefar's adherence to the same

priorities and values as our most prestigious partners.

You have already made an eye-catching foray into the European markets. Do you envision replicating a similar success in the US?

While our main strategy is to grow in Europe, the CIS, and MENA where we have substantial experience, we believe that Birgi Mefar can emerge as a very competitive option for companies looking for a CMO partner for the US market. From both infrastructure and processes standpoints, we are ready to write this next page of our company's history, but we first need to find a business partner who has a range of product dossiers in hand for the US market before applying for US FDA inspection.

Coming back to the Turkish market, an increasing number of pharmaceutical companies started offering contract manufacturing services to multinational companies, in light of Turkey's localization policies. How do you cope with this increasing competition?

This trend has not been a problem for us; frankly speaking, Our value proposition is not to make international companies benefit from spare production capacities but to establish Birgi Mefar's facility as *their* facility.

Since we implemented this strategic direction, we have never lost any customer, while our average customer-length today is around 16 years. Some customers have been partnering with us for more than 25 years.

Furthermore, being one of the 'very few 'pure'' CMOs in Turkey, our positioning avoid any conflict of interest, which is not the case with companies primarily producing and promoting their own product portfolios.

What shall we expect from Birgi Mefar within the next five years?

Our strategy is very clear: we want to increase our business in sterile and injectable products in international markets as well as in the local market localization initiatives. We also plan to develop our added value services and portfolio of critical APIs, with both existing and new customers.

In the grand scheme of things, our vision is to become the primary regional injectables manufacturer for both national and international pharmaceutical players. To fulfil this ambition, we can rely on the experience and technical know-how of our highly seasoned team to provide our partners with products and services of the highest quality standards at optimum cost, in state-of-the-art manufacturing facilities.

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